

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF ALABAMA
EASTERN DIVISION

RECEIVED

PERRY PEARCE BENTON,
Individually and as Administrator
Of the Estate of Robert McIntyre
Pearce, Deceased,

Plaintiff,

v.

GUIDANT CORPORATION
Attn: Legal Department
111 Monument Circle, 29th Floor
Indianapolis, Indiana 46204

And

CARDIAC PACEMAKERS, INC.
c/o The Corporation Company
2000 Interstate Park Drive, Suite 204
Montgomery, Alabama 36109

And

GUIDANT SALES CORPORATION
c/o CSC-Lawyers Incorporating Service
(Corporation Service Company)
150 South Perry Street
Montgomery, Alabama 36104

And

BOSTON SCIENTIFIC
CORPORATION
c/o CSC-Lawyers Incorporating Service
(Corporation Service Company)
150 South Perry Street
Montgomery, Alabama 36104

Defendants.

Case No.:

3:07-cv-493-WHA

2007 JUN 5 10:50
DEBRA P. HACKETT, CLK
U.S. DISTRICT COURT
MIDDLE DISTRICT ALA

COMPLAINT

Jury Demand Endorsed Hereon

Now comes the Plaintiff Perry Pearce Benton (“Plaintiff”), as Personal Representative of the Estate of Robert McIntyre Pearce, deceased (“Decedent”), and for her Complaint against Defendants Guidant Corporation, Cardiac Pacemakers, Inc., Guidant Sales Corporation, and Boston Scientific Corporation (hereinafter collectively referred to as “Defendants”), states the following:

I. THE PARTIES

1. Plaintiff Perry Pearce Benton is a natural citizen residing in the City of Orange Beach, County of Baldwin and State of Alabama.

2. Plaintiff is the duly appointed Administrator of the Estate of Robert McIntyre Pearce, deceased, having been so appointed on October 31, 2005.

3. Decedent Robert McIntyre Pearce was a citizen of Lee County, Alabama.

4. That Plaintiff brings Counts One through Four on behalf of herself and the Estate of said Decedent.

5. On September 2, 2003, Decedent underwent surgical implantation of a Guidant Contak Renewal 3HE, Model H179, Serial Number 100421. The Implantable Cardioverter Defibrillator (“ICD”) was implanted by Kevin P. Ryan, MD, at East Alabama Medical Center in Opelika, Alabama. On September 27, 2005, Decedent passed away.

6. Upon learning of a recall, Decedent was very fearful and anxious about the replacement surgery. However, faced with the significant risk of death or serious injury when his ICD failed, Plaintiff felt he had no choice but to undergo a serious and life threatening surgery to remove the defective ICD and replace it with a new one.

7. The replacement surgery was performed on July 12, 2005, and was performed under conscious and deep sedation by Kevin P. Ryan, MD, at East Alabama Medical Center in Opelika, Alabama. On September 27, 2005, Robert McIntyre Pearce died as a result of complications from this surgery.

8. Decedent suffered from significant pain related to the surgery to replace the defective ICD. In addition to the acute pain and discomfort related to the surgery itself, it took several weeks to recover from the surgery. During this time, Decedent was in significant pain and was not able to do his usual activities.

9. In addition to the physical pain, Decedent also suffered emotional distress as a result of the recall and replacement of his Guidant ICD. Decedent also suffered from fear and anxiety that his new ICD would fail. He lost confidence in the ICD that was supposed to save his life.

10. Defendant Guidant Corporation ("Guidant") is a corporation organized pursuant to the laws of the State of Indiana and maintains its principal place of business in the State of Indiana. Guidant designed, manufactured, marketed, distributed, sold and maintained performance data for their ICD's.

11. Defendant Cardiac Pacemakers, Inc. ("Cardiac"), is a corporation organized pursuant to the laws of the State of Minnesota and maintains its principal place of business in the State of Minnesota. Cardiac designed, manufactured, marketed, distributed, sold and maintained performance data for their ICD's.

12. Defendant Guidant Sales Corporation ("Guidant Sales") is a corporation organized pursuant to the laws of the State of Indiana and maintains its principal place of

business in the State of Indiana. Guidant Sales designed, manufactured, marketed, distributed, sold and maintained performance data for their ICD's.

13. Defendant Boston Scientific purchased Guidant Corporation, and is a corporation organized pursuant to the laws of the State of Delaware, maintains its principal place of business in the State of Massachusetts and is the successor-in-interest of Defendants Guidant, Cardiac and Guidant Sales.

II. NATURE OF THE ACTION

14. On or about May 23, 2005, the Guidant defendants issued a "Dear Doctor" advisory revealing that certain models of Guidant ICD's contain a critical flaw that can result in the failure of the affected ICD's to function properly, leading to injury and/or death. The "Dear Doctor" letter was followed by recalls of Guidants' Contak Renewal, Ventak Prizm, Vitality and Renewal series of ICD's. The Contak Renewal, Ventak Prizm, Vitality and Renewal series of ICD's share a common defect that can result in the failure of the ICD's to properly function when needed. The purpose of an ICD is to prevent cardiac arrest resulting from severe ventricular tachycardia.

15. On April 5, 2007, Defendant Boston Scientific issued a "Product Advisory Letter" revealing that certain models of their ICD's may contain a component within the defibrillator that could cause malfunction, leading to premature battery depletion. The Food and Drug Administration ("FDA") has declared this product advisory as a recall.

III. JURISDICTION AND VENUE

16. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §1332, as the amount in controversy exceeds \$75,000.00 exclusive of interest and costs and because

Plaintiff is a citizen of the State of Alabama and Defendants are citizens of states other than the State of Alabama.

17. Defendants do substantial business in the State of Alabama, advertise in the State of Alabama, and have received substantial compensation and profits from the sale of their ICD's in the State of Alabama, and have engaged in tortious conduct in the State of Alabama.

18. Venue is proper in this district pursuant to 28 U.S.C. §1391. Decedent purchased the product that forms the basis of this lawsuit in the State of Alabama, resided in the Middle District of Alabama and Decedent's ICD was implanted in the Middle District of Alabama.

CAUSES OF ACTION

COUNT I (Negligent Manufacture)

19. Plaintiff reavers and realleges each and every allegation set forth in paragraphs 1 through 18 as though fully rewritten here.

20. Defendants Guidant, Cardiac and Guidant Sales carelessly designed, tested, manufactured, marketed, distributed and sold the Contak Renewal, Ventak Prism, Vitality and Renewal series of ICD's.

21. Defendants were negligent in manufacturing the Contak Renewal, Ventak Prism, Vitality and Renewal series of ICD's because:

- a. The manufacturing processes for the defibrillators and certain components did not satisfy the Food and Drug Administration's Pre-Market Approval standards for the devices; and

- b. The failure of the manufacturing processes for the defibrillators and certain components to satisfy the Food and Drug Administration's Pre-Market Approval standards for the devices resulted in unreasonably dangerous manufacturing defects.

22. Although the Food and Drug Administration's Pre-Marketing Approval process imposed requirements on the Defendants in connection with the manufacture and marketing of Contact Renewal, Ventak Prism, Vitality and Renewal series of ICD's, it did not impose specific health or safety requirements on the device itself.

23. The said negligence of Defendant was a direct and proximate cause of the wrongful death of Decedent, Robert McIntyre Pearce. Plaintiff suffered and continues to suffer expense and economic loss as previously described. The exact amount of Plaintiff's damages will be proven at trial, but they exceed the jurisdictional minimum of this Court. Defendants are strictly liable for said damages.

COUNT II
(Negligent/Flagrant Failure to Warn)

24. Plaintiff reavers and realleges each and every allegation set forth in paragraphs 1 through 23 as though fully rewritten herein.

25. For approximately three (3) years prior to the implantation of Plaintiff's Guidant ICD, Defendants were aware that the Contak Renewal, Ventak Prism, Vitality and Renewal series of ICD's shared a defect that could result in the failure of Contak Renewal, Ventak Prism, Vitality and Renewal series of ICD's to function properly.

26. Decedent's Guidant ICD was implanted after Defendants became aware of the common defect that could result in the failure of the Contak Renewal, Ventak Prism, Vitality and Renewal series of ICD's to function properly.

27. Defendants acted negligently, recklessly, maliciously and with flagrant disregard of Decedent's safety in failing to warn Decedent and/or Decedent's Physicians, prior to the implantation of their ICD's, of the defects in their Contak Renewal, Ventak Prism, Vitality and Renewal series of ICD's.

28. That as a direct and proximate result of Defendants' negligent, reckless, malicious and flagrant disregard for Decedent's safety, Decedent suffered injuries and ultimately death.

29. That as a further direct and proximate result of Defendants' flagrant and malicious disregard for Decedent's safety, Plaintiff is entitled to punitive damages.

COUNT III
(Product Liability: Manufacturing Defect)

30. Plaintiff reavers and realleges each and everly allegation set forth in paragraphs 1 through 29 as though fully rewritten herein.

31. Defendants produced, manufactured, supplied, created, tested and marketed the Contak Renewal, Ventak Prism, Vitality and Renewal series of ICD's, which Defendants intended to sell or distribute to persons for commercial and/or personal use. Said ICD's were tangible personal property.

32. That the Contak Renewal, Ventak Prism, Vitality and Renewal series of ICD's were defective in manufacture, because when they left the Defendants' control, said ICD's deviated in a material way from the Defendants' design specifiications and performance standards.

33. That Defendants' Contak Renewal, Ventak Prism, Vitality and Renewal series of ICD's reached Decedent in the same or substantially same condition as said ICD's were in at the time they left the Defendants' control.

34. That the manufacturing defects in Defendants' ICD's created a foreseeable risk of harm to Decedent and rendered the Defendants' ICD's unsafe and unreasonable dangerous.

35. The said manufacturing defect of Defendant was a direct and proximate cause of the wrongful death of Decedent, Robert McIntyre Pearce. The exact amount of Plaintiff's damages will be proven at trial, but they exceed the jurisdictional minimum of this Court. Defendants are strictly liable for said damages.

COUNT IV
(Product Liability: Post-Marketing Warnings)

36. Plaintiff reavers and realleges each and every allegation set forth in paragraphs 1 through 35 as though fully rewritten herein.

37. Defendants Contak Renewal, Ventak Prism, Vitality and Renewal series of ICD's were defective due to inadequate post-marketing warnings and instructions because after said ICD's received pre-market approval from the Food and Drug Administration pursuant to 21 U.S.C. §360c and after said ICD's left the Defendants' control:

- a. The Defendants knew or, in the exercise of reasonable care, should have known about the risk of failure of their ICD's; and
- b. The Defendants failed to provide the post-marketing warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that the product would cause harm of the type for which the Plaintiff seeks to recover damages and in light of the likely seriousness of that harm.

38. That Defendants' failure to provide the post-marketing warnings and instructions to Decedent concerning the risk that their Contak Renewal, Ventak Prism,

Vitality and Renewal series of ICD's could fail or otherwise suffer from a defect that create a risk of injury and/or death, rendered Defendants' ICD's defective and unreasonable dangerous.

39. The said failure to provide the post-marketing warnings and instructions concerning a defect and/or risk of harm associated with Contak Renewal, Ventak Prism, Vitality and Renewal series of ICD's was a direct and proximate cause of the wrongful death of Decedent, Robert McIntyre Pearce. The exact amount of Plaintiff's damages will be proven at trial, but they exceed the jurisdictional minimum of this Court. Defendants are strictly liable for said damages.

WHEREFORE, Plaintiff requests that this Court enter a judgment against Defendants Guidant Corporation, Cardiac Pacemakers, Inc., and Guidant Sales Corporation in favor of Plaintiff and award the following relief:

- A. Compensatory damages against Defendants Guidant Corporation, Cardiac Pacemakers, Inc., and Guidant Sales Corporation, jointly and severally, in excess of \$75,000.00, exclusive of interest and costs;
- B. Punitive damages against Defendant Guidant Corporation, Cardiac Pacemakers, Inc., and Guidant Sales Corporation;
- C. Equitable, injunctive relief in the form of a medical monitoring program, to be established and supervised by the Court and funded by the Defendants Guidant Corporation, Cardiac Pacemakers, Inc., and Guidant Sales Corporation for the benefit of Plaintiff;
- D. Prejudgment and post-judgment interest on all damages;

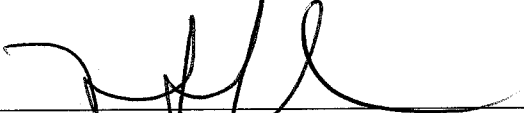
- E. Costs, including expert fees and attorney fees incurred in the prosecution of this action; and
- F. Such other and further relief that the court deems just and proper.

JURY DEMAND

Pursuant to Rule 38(b), Federal Rules of Civil Procedure, Plaintiff hereby demands trial by jury.

Dated: 6/4/07

**BEASLEY, ALLEN, CROW,
METHVIN, PORTIS & MILES, P.C.**



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